

LAW OFFICES

NOSSAMAN, GUTHNER, KNOX & ELLIOTT, LLP

WALTER L. NOSSAMAN
(1986-1984)

WILLIAM E. GUTHNER, JR.
(1932-1999)

LOS ANGELES
THIRTY-FIRST FLOOR
445 SOUTH FIGUEROA STREET
LOS ANGELES, CA 90071-1602
(213) 612-7800

IRVINE
SUITE 1600
18101 VON KARMAN AVENUE
IRVINE, CA 92612-0177
(949) 833-7800

THIRTY-FOURTH FLOOR
50 CALIFORNIA STREET
SAN FRANCISCO, CALIFORNIA 94111-4799
TELEPHONE (415) 398-3800
FACSIMILE (415) 398-2438

CAROL RENÉ BROPHY
EMAIL: cbrophy@nossaman.com

JOHN T. KNOX
WARREN G. ELLIOTT
OF COUNSEL

WASHINGTON, D.C./VIRGINIA
SUITE 800
2111 WILSON BOULEVARD
ARLINGTON, VA 22201-3052
(703) 351-8010

SACRAMENTO
SUITE 1000
915 L STREET
SACRAMENTO, CA 95814-3705
(916) 442-8888

September 13, 2004

VIA FEDERAL EXPRESS

REFER TO FILE NUMBER

280090 - 0001

George Alexeeff, Ph.D.
Deputy Director of Scientific Affairs
Office of Environmental Health Hazard Assessment
1515 Clay Street, 16th Floor
Oakland, California 94912

**Re: Supplemental Information Submittal – Petition for Safe Use Determination for
[REDACTED] – Transfer Factor for Lead**

Dear Dr. Alexeeff:

We have received your letter of September 7, 2004. Enclosed please find our check number 4004214 in the amount of \$500.00 in payment of the fee for OEHHA to consider the Fishing Coalition's Request for a Regulatory Interpretation, as a Safe Use Determination. [REDACTED]

[REDACTED] Thus, OEHHA should now have received the two \$500.00 checks it is requesting: [REDACTED] and \$500 for consider the Request for Regulatory Interpretation as an SUD.

Your letter also indicated that OEHHA found the Request for Regulatory Interpretation too broad, and requested that the Fishing Coalition narrow its scope by identifying the chemical that is the subject of the request. We apologize for the confusion and clarify it now. *The chemical at issue is "lead"; the products at issue are the fishing tackle products that are the* [REDACTED]

[REDACTED] More significantly, the substrates at issue in the "Lead Transfer Factor" will be pvc, plastic, painted surfaces, and metal alloy surfaces, (e.g., any substrate which may "leach" lead from its surface in a manner that an individual may come in contact with lead or lead compounds as a result of handling the fishing tackle product (e.g., its substrate).

Because the Transfer Factor SUD and [REDACTED] concern the same chemical (lead), and the same products (fishing tackle), we assume that all of the information and data that was submitted on July 21, 2004 will be used to evaluate both SUDs. We further assume that with the payment of the evaluation fees and this clarification letter that OEHHA will begin review of the substantive issues. If by recharacterizing the Request for Regulatory Interpretation as an SUD, OEHHA requires that we copy all of the information and supporting technical data which was submitted [REDACTED] and submit it under a new petition, please contact us immediately so that we can provide the reformatted request this week.

George Alexeeff, Ph.D.

September 13, 2004

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We would like to emphasize why OEHHHA's prompt evaluation of the Transfer Factor SUD is of paramount importance. Unless and until OEHHHA provides a clear and definitive procedure to quantify the level of exposure for "indirect exposures" -- when lead on the surface of fishing tackle substrates is handled -- it is impossible for a for manufacturers, distributors and retailers of fishing tackle to determine whether a Proposition 65 warning is required or not. Moreover, if OEHHHA does not provide such guidance, industry may not be able to sustain its burden of proof in a Proposition 65 enforcement action. (This has already occurred in *DiPirro v. Macy*.) It is one thing to be found liable on the merits (where an exposure exceeds the warning threshold) and quite another to be liable because there is no state approved procedure for quantifying the exposure at issue. We ask OEHHHA to help us, and all industry, by providing guidance. Failure to do so will only leave California businesses exposed to more frivolous lawsuits.

[REDACTED]

The "Transfer Factor SUD" will provide this guidance, and will enable the Fishing Tackle Coalition and their many customers will be able to have way to evaluate the many products that are not specifically included in [REDACTED]

Thus, ***unless and until OEHHHA provides guidance on how such "hand to mouth" exposures may be quantified, all business are at risk.*** As OEHHHA is aware, it is not possible to quantify exposures by determining the total amount of lead in a fishing tackle product, because there is no relationship between the lead bound in the substrate and the lead ingested. We believe there is a relationship between the amount of lead that migrates to the surface, and which can be measured in a simple wipe test, and the amount subsequently assumed to be ingested.

As the Fishing Tackle Coalition will need OEHHHA's response to these SUDs to prepare for the 2005 fishing season, time is of the essence. Please contact me by e-mail at cbrophy@nossaman.com or by telephone if you have any questions or require any further information. Thank you for your assistance.

Sincerely,



Carol René Brophy
OF NOSSAMAN, GUTHNER, KNOX & ELLIOTT, LLP

Enclosure

cc: Carol Monahan, Esq. (via fax)
Val F. Siebal, Chief Deputy Director, OEHHHA (via fax)
Joan Denton, Director OEHHHA (via fax)

LAW OFFICES

NOSSAMAN, GUTHNER, KNOX & ELLIOTT, LLP

WALTER L. NOSSAMAN
(1886-1964)

WILLIAM E. GUTHNER, JR.
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LOS ANGELES
THIRTY-FIRST FLOOR
445 SOUTH FIGUEROA STREET
LOS ANGELES, CA 90071-1602
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IRVINE
SUITE 1800
18101 VON KARMAN AVENUE
IRVINE, CA 92612-0177
(949) 833-7800

THIRTY-FOURTH FLOOR
50 CALIFORNIA STREET
SAN FRANCISCO, CALIFORNIA 94111-4799
TELEPHONE (415) 398-3600
FACSIMILE (415) 398-2438

CAROL RENÉ BROPHY
EMAIL: cbrophy@nossaman.com

JOHN T. KNOX
WARREN G. ELLIOTT
OF COUNSEL

WASHINGTON, D.C./VIRGINIA
SUITE 600
2111 WILSON BOULEVARD
ARLINGTON, VA 22201-3052
(703) 351-5010

SACRAMENTO
SUITE 1000
915 L STREET
SACRAMENTO, CA 95814-3705
(916) 442-8888

July 21, 2004

OFFICE OF ENVIRONMENTAL HEALTH
HAZARD ASSESSMENT
Received
JUL 30 2004
Sacramento

REFER TO FILE NUMBER
280090 - 0001

VIA FACSIMILE AND FIRST-CLASS MAIL

George Alexeeff, Ph.D.
Deputy Director of Scientific Affairs
Office of Environmental Health Hazard Assessment
1515 Clay Street, 16th Floor
Oakland, California 94912

**Re: Supplemental Information Submittal – Petition for Safe Use Determination for
[REDACTED] and Interpretive Guideline Request**

Dear Dr. Alexeeff:

[REDACTED]

As a separate request, the Coalition asks that OEHHA provide an Interpretive Guideline Request concerning the way that consumer product exposure assessments should be conducted. Specifically, the Coalition seeks guidance (in the form of a methodology, a formula, or other easily applied transfer factors) that will enable the regulated community to evaluate “indirect” exposures by the ingestion pathway—where the exposure travels from the surface of a consumer product to the mouth by transferring one or more times to a series of objects.

The following documents are enclosed:

1. [REDACTED]
2. *Interpretive Guideline Request.*

George Alexeeff, Ph.D.
July 21, 2004
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[REDACTED]

Background and Purpose. The Coalition makes this request to avoid “over-warning.” As OEHHA is aware, the sportfishing industry has been the target of private enforcement actions resulted in settlements that require Proposition 65 warnings where minute, albeit “detectable”, amounts of a listed chemical are present. The Coalition finds itself in this regrettable situation because Proposition 65 does not hold “private plaintiffs” to the same evidentiary standards as defendants, allowing them to file an enforcement action on the slimmest suggestion of a detectable exposure. At trial, the burden is on the defendant to provide evidence the exposure does not pose a “significant risk assuming lifetime exposure at the level in question for a substance known to the state to cause cancer,” and/or the “exposure will not have an...observable effect assuming exposure at one thousand times the level in question for substances known to the state to cause reproductive harm.” Health & Safety Code §25249.10(c).

The fishing tackle industry has been presented with a Hobson’s choice. Even when a company knows the use of its products causes exposures well below the warning levels, the company must either provide warnings when *any* detectable exposure is possible, or remove the frivolous warning knowing that it faces a prohibitively expensive and lengthy trial if a “private plaintiff” strikes. For most businesses, the choice is simple: provide the warning, even if the collective effect undermines the utility of all warnings. Although SB 471 was adopted by the California Legislature in 2001 to abate meritless Proposition 65 enforcement actions, as a practical matter it has been of little help where, as here, a consumer product contains a detectable amount of a listed chemical, and *there are no OEHHA-approved procedures or guidelines that the regulated community may use to prove that the exposure is below the warning threshold.*

[REDACTED]

The Coalition further requests a determination that the suggested method is an appropriate means by which to determine if other Coalition members’ fishing tackle products also require a warning

The Coalition is further requesting an Interpretive Guideline, because there are no state-approved methodologies for performing exposure assessments for background lead in consumer products such as fishing tackle. Moreover, there are *no* verified protocols for evaluating exposures to lead via the ingestion pathway from consumer products where the exposure is caused by handling the product and subsequently putting hands or food in the mouth. Because the “hand-to-mouth” ingestion route is the significant exposure route for fishing tackle, the Coalition is requesting that OEHHA issue an Interpretive Guideline specifying the transfer factor that should be used to estimate the hand-to-mouth exposure. Importantly, as new test methods are capable of detecting lower and lower levels of chemicals, *virtually every consumer product* will have quantifiable background levels of one or more listed chemicals. Thus, this Interpretive Guideline will make it possible for the larger regulated community to estimate exposures from handling consumer products.

George Alexeeff, Ph.D.

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

If you have any questions concerning this submittal, I will be happy to answer them.
Thank you for your courtesy and consideration in this matter.

Sincerely,



Carol René Brophy
Of NOSSAMAN, GUTHNER, KNOX & ELLIOTT, LLP

Enclosures (2)

cc: Carol Monahan, Esq.

Val F. Siebal, Chief Deputy Director, OEHHA

² The recent EPA and the Consumer Product Safety Commission study evaluating exposure to CCA-treated wood products (U.S. EPA 2003 *A Probabilistic Exposure Assessment for Children Who Contact CAA-Treated Playsets and Decks Using a Stochastic Human Exposure and Dose Simulation Model*. Draft Final Report; <http://www.epa.gov/scipoly/sap/2003>)

THE SPORTS FISHING COALITION

INTERPRETIVE GUIDELINE REQUEST

Carol René Brophy
Michele A. Boddy

Nossaman, Guthner, Knox, Elliot LLP
San Francisco, CA 94111
(415) 438-7267

July 21, 2004

INTERPRETIVE GUIDELINE REQUEST

The Sports Fishing Coalition¹ ("Coalition") hereby petitions the Office of Environmental Health Hazard Assessment ("OEHHA") for an Interpretive Guideline pursuant to Title 22 of the California Code of Regulations Section 12203 concerning the way that Proposition 65 exposure assessments should be conducted where the exposure results from handling a consumer product. Specifically, the Coalition seeks guidance (in the form of a methodology, a formula, or other easily applied factors) that will enable the regulated community to evaluate "indirect" exposures by the ingestion pathway—where the exposure travels from the surface of a consumer product to the mouth by transferring one or more times to a series of objects.

OEHHA's guidance on this issue is urgently needed, because there are no state-approved methodologies for performing exposure assessments for background lead in consumer products, such as fishing tackle. Moreover, there are no verified protocols for evaluating exposures via the ingestion pathway from consumer products where the exposure is caused by handling the product and subsequently putting hands, items, or food in the mouth. The Coalition notes that virtually all substrates such as plastic, vinyl, or metal have *some detectible* amount of one or more Proposition 65 listed chemicals, generally present as a background contaminant. Because the "hand to mouth" ingestion route is the significant exposure route for fishing tackle, the Coalition is requesting that OEHHA issue an Interpretive Guideline specifying the transfer factor that should be used to estimate the hand-to-mouth ingestion exposure. Importantly, as new test methods are capable of detecting lower and lower levels of chemicals in the environment, virtually *every consumer product* will have quantifiable background levels of one or more listed chemicals. Thus, this Interpretive Guideline will make it possible for the larger regulated community to estimate exposures from handling consumer products.

Concurrent with this Interpretive Guideline Request, [REDACTED]

[REDACTED] Some of the information submitted in support of the SUD may be helpful to OEHHA as it reviews this request. [REDACTED]

[REDACTED] The methodology uses a NIOSH 9100 wipe test to pick up the contaminant, measures the result, and then uses a transfer factor to estimate the amount of contaminant that may enter the mouth. Although known to overstate the exposure, the proposed methodology has the benefit of simplicity and has been used by Proposition 65 prosecutors (the Office of the Attorney General), and by US EPA to

¹ The Coalition members are: Acme Tackle Company, Cabela's, PRADCO Outdoor Brands, PureFishing, Normark Corp., Shakespeare Fishing Tackle, Yakima Bait Company, and Zebco.

evaluate consumer product exposures from chemical in children's play sets.³ In these cases, the transfer factor used was 5%.

Although the "wipe amount x transfer factor" methodology has the benefit of ease of use, it does not fit comfortably with Proposition 65's implementing regulations, Cal. Code Reg., tit. 22 §12721 (carcinogens) and Cal. Code Reg., tit. 22 §12821 (reproductive toxins). Equations that work for direct exposures (where the chemical is eaten in food, or breathed in air) do not work well for indirect exposures (where the chemical is transferred from source to hand to an item, e.g., cigarette or food, to mouth). To illustrate using the No Significant Risk level for carcinogens⁴, Cal. Code Reg., tit 22 §12721(b) provides that exposure to a consumer product poses no significant risk of cancer if the "concentration of the chemical in the given medium" multiplied by the "reasonably anticipated rate of exposure for an individual to that given medium" is less than the specified No Significant Risk level.⁵ This process is described numerically by the following equation:

$$\begin{array}{lcl} \text{Concentration of a chemical in} & \times & \text{Reasonably anticipated rate of exposure} \\ \text{a given medium} & & \text{to the given medium}^6 \end{array} < \text{NSRL}$$

In the case of indirect exposures, the "concentration of a chemical in a given medium" is not capable of direct measurement, and the term itself is imprecise and misleading. Because the chemical is transferred several times, only a percentage of the total available chemical is ingested. In the case of consumer products, like fishing tackle, which are not put into the mouth, any ingestion of a chemical on the consumer product's surface will be the product of at least two to four transfers – for example: 1) product surface to hand, 2) hand to food; or 1) product surface to hand, 2) hand to lips, and 3) lips into the mouth via tongue; or 1) product surface to hand, 2) hand to cigarette, 3) cigarette to lips, and 4) lips into the mouth via tongue. Thus, "concentration of chemical in a given medium" in the instance may be characterized as "the amount of chemical available for transfer on the surface of the item that is put in the mouth or on the tongue x a transfer factor". In this case, OEHHA would need to establish the "transfer factor".

* * *

We trust that we have explained our request in sufficient detail for OEHHA to act on it.

³ U.S. EPA 2003. *A Probabilistic Exposure Assessment for Children Who Contact CCA-Treated Playsets and Decks Using the Stochastic Human Exposure and Dose Simulation Model* – Draft Final Report, <http://www.epa.gov/scipoly/sap/2003>

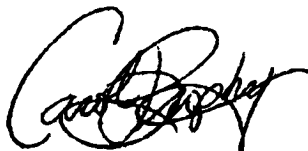
⁴ A similar analysis for reproductive toxins using Cal. Code Reg., tit. 22 §12821.

⁵ Cal. Code Reg., tit. 22 §12721(a).

⁶ Cal. Code Reg., tit 22 §12721(b).

Thank you for your consideration of this request. If you require additional information or further clarification, we will be pleased to provide it.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Carol Brophy", written in a cursive style.

Carol René Brophy
of NOSSAMAN, GUTHNER, KNOX & ELLIOTT, LLP